

§ 862.3030

required for the plasma to flow a measured distance through a calibrated glass tube. Measurements obtained by this device are used to monitor changes in the amount of solids present in plasma in various disorders.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

[52 FR 16122, May 1, 1987, as amended at 60 FR 38900, July 28, 1995; 66 FR 38788, July 25, 2001]

Subpart D—Clinical Toxicology Test Systems

§ 862.3030 Acetaminophen test system.

(a) *Identification*. An acetaminophen test system is a device intended to measure acetaminophen, an analgesic and fever reducing drug, in serum. Measurements obtained by this device are used in the diagnosis and treatment of acetaminophen overdose.

(b) *Classification*. Class II.

§ 862.3035 Amikacin test system.

(a) *Identification*. An amikacin test system is a device intended to measure amikacin, an aminoglycoside antibiotic drug, in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of amikacin overdose and in monitoring levels of amikacin to ensure appropriate therapy.

(b) *Classification*. Class II.

§ 862.3040 Alcohol test system.

(a) *Identification*. An alcohol test system is a device intended to measure alcohol (e.g., ethanol, methanol, isopropanol, etc.) in human body fluids (e.g., serum, whole blood, and urine). Measurements obtained by this device are used in the diagnosis and treatment of alcohol intoxication and poisoning.

(b) *Classification*. Class II.

§ 862.3050 Breath-alcohol test system.

(a) *Identification*. A breath-alcohol test system is a device intended to measure alcohol in the human breath. Measurements obtained by this device

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are used in the diagnosis of alcohol intoxication.

(b) *Classification*. Class I.

§ 862.3080 Breath nitric oxide test system.

(a) *Identification*. A breath nitric oxide test system is a device intended to measure fractional nitric oxide in human breath. Measurement of changes in fractional nitric oxide concentration in expired breath aids in evaluating an asthma patient's response to anti-inflammatory therapy, as an adjunct to established clinical and laboratory assessments of asthma. A breath nitric oxide test system combines chemiluminescence detection of nitric oxide with a pneumotachograph, display, and dedicated software.

(b) *Classification*. Class II (special controls). The special control is FDA's guidance entitled "Class II Special Controls Guidance Document: Breath Nitric Oxide Test System." See § 862.1(d) for the availability of this guidance document.

[68 FR 40127, July 7, 2003]

§ 862.3100 Amphetamine test system.

(a) *Identification*. An amphetamine test system is a device intended to measure amphetamine, a central nervous system stimulating drug, in plasma and urine. Measurements obtained by this device are used in the diagnosis and treatment of amphetamine use or overdose and in monitoring levels of amphetamine to ensure appropriate therapy.

(b) *Classification*. Class II.

§ 862.3110 Antimony test system.

(a) *Identification*. An antimony test system is a device intended to measure antimony, a heavy metal, in urine, blood, vomitus, and stomach contents. Measurements obtained by this device are used in the diagnosis and treatment of antimony poisoning.

(b) *Classification*. Class I.

§ 862.3120 Arsenic test system.

(a) *Identification*. An arsenic test system is a device intended to measure arsenic, a poisonous heavy metal, in urine, vomitus, stomach contents, nails, hair, and blood. Measurements